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RULE PROPOSAL
HEALTH AND SENIOR SERVICES
DIVISION OF SENIOR BENEFITS AND UTILIZATION MANAGEMENT
OBLIGATIONS OF PAAD-PARTICIPATING PHARMACIES WITH REGARD TO PAAD RECOVERY OF BENEFITS FROM MEDICARE

Proposed New Rules: N.J.A.C. 8:83C-1.2 and 1.4

Proposed Amendments: N.J.A.C. 8:83-2.1 and 4.2

Proposed Recodification with Amendments: N.J.A.C. 8:83C-1.2 as 1.3; 1.3 through 1.6 as 1.5 through 1.8; 1.8 and 1.9 as 1.10 and 1.11; 1.11 as 1.13; 1.13 and 1.14 as 1.15 and 1.16; 1.19 as 1.21; 1.21 as 1.23; and 1.25 and 1.26 as 1.27 and 1.28

Authorized By: Clifton R. Lacy, M.D.
Commissioner
Department of Health and Senior Services

Authority: N.J.S.A. 30:40D-20 et seq.; New Jersey Appropriations Act, P.L. 2001, c.130; and 42 U.S.C. §§ 1395 et seq.

Calendar Reference: See Summary below for explanation of the exception to the calendar requirement.

Proposal **Number**: PRN 2002-352.

Submit comments by December 6, 2002 to:

Kathleen Mason, Assistant Commissioner
Division of Senior Benefits and Utilization Management
PO Box 715
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The agency proposal follows:

Summary

The Division of Senior Benefits and Utilization Management, Department of Health and Senior Services, is the designated agency with responsibility for operating the Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program.

Beneficiaries must agree to assign to PAAD any right to drug benefits to which they may be entitled under any other third party insurance or assistance plan. N.J.A.C. 8:83-5.6(c)4. Certain prescription drugs and medical supply services are eligible for benefits from both PAAD and the Federal Medicare program. 42 U.S.C. §§ 1395 et seq.

All PAAD beneficiaries are eligible for Medicare benefits with the exception of disabled persons in the first two years of their disability. There are approximately 190,000 PAAD beneficiaries, including approximately 24,000 disabled persons.

The purpose of this rulemaking proposal is to clarify the procedures that pharmacies must follow so that PAAD may carry out the Medicare Recovery initiative.

Under the proposed amendments and new rules, New Jersey pharmacies are required to apply for and maintain active status as Medicare Part B Suppliers in order to participate in PAAD, and must provide PAAD with proof of enrollment at the time of application for a PAAD/Medicaid provider **number**. The Medicare enrollment requirement was established by the New Jersey Appropriations Act, P.L. 2000, c.53, and continued by P.L. 2001, c.130.

As Medicare suppliers, pharmacies are required to comply with the Medicare documentation requirements outlined in its Supplier Manual, including retention of a written order from the physician containing the patient's diagnosis code. A diagnosis code is not presently required for PAAD claims.

In addition, pharmacies must complete an Electronic Data Interchange (EDI) Enrollment Form that permits PAAD to bill Medicare electronically for eligible claims. PAAD will act as billing agent for the pharmacies through a contract vendor for these dually eligible claims. Medicare will then reimburse the pharmacies directly for its allowable amount, and PAAD will recapture the funds by withholding the amount of the reimbursement from future PAAD claims. It is estimated that PAAD will recoup over $4,400,000 annually from the Medicare Recovery initiative.

Representatives of the long-term care pharmacy community have expressed that this population has special concerns with regard to dispensing and billing issues. PAAD is cooperating with the long-term care pharmacies in identifying and resolving those issues.

The addition of the new section to Chapter 83C describing the Medicare Recovery initiative requires the creation of a "definitions" section to explain the terms used in the new section. Because the new sections will be added to the beginning of the chapter, recodification of the current sections is necessary. The new definitions section is proposed N.J.A.C. 8:83C-1.2.

Former N.J.A.C. 8:83C-1.2, Participation of eligible providers, will become N.J.A.C. 8:83C-1.3 and will contain new language referring to the Medicare Recovery initiative. The new section on the Medicare Recovery initiative is N.J.A.C. 8:83C-1.4. All other sections will advance their codification by two, for example, N.J.A.C. 8:83C-1.3 will become N.J.A.C. 8:83C-1.5. Paragraphs related to the Medicare Recovery initiative will be added to N.J.A.C. 8:83C-1.10, PAAD program co-payment (formerly N.J.A.C. 8:83C-1.8), and N.J.A.C. 8:83C-1.16, Quantity of medication (formerly N.J.A.C. 8:83C-1.14). With the exception of the above-noted amendments, the recodification of Chapter 83C involves only the renumbering of the sections and of their associated internal references.

Social Impact

The PAAD program provides prescribed legend drugs, insulin, insulin supplies, and diabetic testing materials to eligible New Jersey residents at a copayment of $5.00 per prescription to the beneficiary. To be eligible, New Jersey residents must be at least 65 years of age or older, or be permanently and totally disabled and a recipient of Social Security Title II benefits, while having an annual income below a prescribed amount that is adjusted annually by the amount of the Social Security Cost-of-Living Allowance. Implementation of the Medicare Recovery initiative will allow PAAD to achieve a cost saving to New Jersey taxpayers while maintaining its present and future planned level of service to beneficiaries.

The population most affected by the proposed new rules and amendments will be PAAD-participating pharmacies, whose responsibilities are specified in the Regulatory Flexibility Analysis below. Long-term care pharmacies in particular have special concerns of maintaining compliance with Medicare's dispensing and billing regulations under the proposed new rules and amendments. Beneficiaries will not be directly impacted by the new requirements, except that they should ensure that their physician write a diagnosis code on their prescription or Certificate of Medical Necessity. Likewise, physicians will need to ensure that they place a diagnosis code on any written order eligible for PAAD Medicare reimbursement.

Economic Impact

There are approximately 190,000 PAAD beneficiaries, including approximately 24,000 disabled persons. PAAD sustains benefit costs (net of current rebate and recovery programs) of nearly $300,000,000 per year. PAAD estimates that it can recover over $4,400,000 annually from Medicare for dually eligible drugs and supplies. Otherwise, there is no specific economic impact associated with the proposed new rules and amendments. There will be no economic impact on beneficiaries and de minimus impact on providers.

Federal Standards Statement

The Department of Health and Senior Services certifies that a Federal standards analysis is not applicable, as the proposed new rules and amendments are subject to, but do not exceed, requirements of 42 U.S.C. §§ 1395 et seq., and 42 CFR §§ 400-429.

Jobs Impact

The proposed new rules and amendments will have no impact on the generation or loss of jobs. Based upon the six-month pilot program the impact on the generation or loss of jobs and any associated economic impact has been de minimus.

Agriculture Industry Impact

The proposed new rules and amendments will have no impact on the agriculture industry.

Regulatory Flexibility Analysis

The proposed new rules and amendments impose reporting, recordkeeping or other compliance requirements on small businesses, as defined under the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as follows:

1. All New Jersey pharmacies that participate in the PAAD program are mandated to comply with the Medicare Recovery initiative requirements. Approximately 785 small businesses are affected by these proposed new rules and amendments.

2. Pharmacies must enroll as a Medicare Part B supplier and maintain active status, which requires completion of an application form and attachment of numerous proofs of such requirements as State-issued pharmacy license **number**, liability insurance, and Federal employer identification **number**. Reapplication must be made every three years.

3. Pharmacies must comply with all Medicare documentation requirements, including ensuring that the patient's diagnosis code is recorded by the doctor on every Medicare-eligible

written order and retaining records for the specified period of time. Records are subject to inspection by representatives of Medicare and of PAAD. Noncompliance with recordkeeping requirements subjects pharmacies to potential fines, penalties, and withdrawal of participation from the Medicare program, which in turn will jeopardize their PAAD enrollment.

4. Pharmacies must provide PAAD with proof of Medicare Part B enrollment. They must also complete and return a two-page Electronic Data Interchange (EDI) Enrollment Form permitting PAAD to bill Medicare electronically on their behalf. Lack of compliance with these requirements will cause a pharmacy to have their PAAD provider status suspended until these items are submitted, resulting in delayed payments to the pharmacy and inconvenience and potential interruption of service to beneficiaries.

5. Pharmacies will continue to submit eligible claims to PAAD as usual, except that the diagnosis code will be collected by telephone until PAAD's electronic claim system can be updated to capture this figure. Pharmacies may need to contact the physician to obtain the diagnosis code if it is not written on the order. Orders that do not conform to dispensing guidelines will require the pharmacies to call the physician to have the order rewritten.

6. Because PAAD acts as a billing agent for the pharmacies under 42 CFR § 424.73, Medicare will pay its allowable amount for claims directly to the pharmacies. PAAD will collect the reimbursement by withholding the amount paid to the pharmacies by Medicare from future PAAD claim payments. This process will increase the need for accounting review for the pharmacies as well as for PAAD.

7. Pharmacies must cooperate in the investigation of discrepancies in any claims, whether discovered by the pharmacy, PAAD, Medicare, or the beneficiary, and take any corrective action needed.

8. Long-term care pharmacies need to remain compliant with Medicare regulations particular to their industry while accommodating the proposed new PAAD rules and amendments.

9. Physicians and other health care providers authorized to write prescriptions need to be aware of and comply with the requirements that PAAD patients have a diagnosis code written on orders eligible for Medicare reimbursement. Health care providers are sent a copy of all relevant PAAD-generated newsletters to the pharmacy community and should thus be aware of the requirement. However, health care providers do not necessarily know that a particular patient or drug/supply is PAAD or Medicare-eligible. Therefore, it is likely that physicians will be inconvenienced on occasion by having to rewrite orders to comply with the Medicare documentation and dispensing requirements.

The establishment of different performance standards for small business is not practicable for the purpose of the proposed rules and amendments. PAAD will take advantage of all possible improvements in technological and operational efficiencies to minimize the burden on pharmacies. PAAD has involved the pharmaceutical associations and other industry representatives in the planning of the Medicare Recovery initiative and will continue to solicit input from the pharmacy community to improve the operation of the program. The changes encompassed by these proposed rules and amendments have been implemented on a pilot basis for a period of six months. During that period, small businesses have not reported any undue financial burdens or inability to comply with the procedures. There will be no need to employ professional services, such as financial services personnel, because these functions are, for the most part, performed by existing staff.

Smart Growth Impact

The proposed new rules and amendments will have no impact on the achievement of smart growth and will have no effect on the implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows:

CHAPTER 83
PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED ELIGIBILITY MANUAL

SUBCHAPTER 2. DEFINITIONS

<< NJ ADC 8:83-2.1 >>

8:83-2.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

...

"Centers for Medicare and Medicaid Services (CMS)" means the agency of the Federal Department of Health and Human Services which is responsible for the administration of the Medicare program in the United States. CMS was formerly known as the Health Care Financing Administration (HCFA).

...

"Electronic Data Interchange (EDI) Enrollment Form" means an agreement signed by a Medicare Part B Supplier authorizing PAAD to bill Medicare electronically on its behalf for claims that are eligible under both PAAD and Medicare.

...

"Medicare" means medical assistance provided to certain aged and disabled persons as authorized under Title XVIII (Medicare) of the Social Security Act.

"Medicare Part B Supplier" means a supplier of Medicare Part B (Medical Insurance) services to Medicare beneficiaries including Durable Medicare Equipment, Prosthesis, Orthotics, and Supplies (DMEPOS).

"National Suppliers Clearinghouse (NSC)" means the entity that issues Durable Medicare Equipment, Prosthesis, Orthotics, and Supplies (DMEPOS) supplier authorization **numbers** nationwide to Medicare Part B Suppliers for the Centers for Medicare and Medicaid Services (CMS). The National Supplier Clearinghouse is located at P.O. Box 100142, Columbia, SC 29202-3142.

"NSC Supplier **Number**" means the authorization **number** issued by the National Supplier Clearinghouse (NSC) to a Medicare Part B Supplier of Durable Medicare Equipment, Prosthesis, Orthotics, and Supplies (DMEPOS) for the Centers for Medicare and Medicaid Services (CMS).

...

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products contained in the latest list approved and published by the Drug Utilization Review Council in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, insulin needles and certain diabetic testing materials when prescribed.

1. (No change.)

2. The term "prescription drugs" excludes cosmetics drugs as indicated at N.J.A.C. 8:83C-1.13-1.15 unless medically necessary.

SUBCHAPTER 4. SCOPE OF SERVICE

<< NJ ADC 8:83-4.2 >>

8:83-4.2 Principles of reimbursement to participating pharmacies

(a) Reimbursement for PAAD prescriptions will be made only to pharmacies located in New Jersey and operating under a valid permit from the Board of Pharmacy of the State of New Jersey. In order to become an approved provider, such a pharmacy must file an application and agreement of participation which must be approved by the Division of Medical Assistance and Health Services of the Department of Human Services. The application shall contain the pharmacy's NSC Supplier **Number** issued by the National Supplier Clearinghouse (NSC) or other appropriate agent of the Centers for Medicare and Medicaid Services (CMS) or a statement that the pharmacy has applied for a NSC Supplier **Number** to enroll as a Medicare Part B supplier. A copy of one of the proofs of enrollment listed in N.J.A.C. 8:83C-1.3(c)2 shall be attached to the application. The pharmacy shall also complete and return the Electronic Data Interchange (EDI) Enrollment Form attached to the application.

(b)-(c) (No change.)

CHAPTER 83C
PROVISION OF PHARMACEUTICAL SERVICES UNDER THE PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED PROGRAM (PAAD)

SUBCHAPTER 1. REQUIREMENTS FOR PROVISION OF PHARMACEUTICAL SERVICES

<< NJ ADC 8:83C-1.2 >>

8:83C-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise.

"Annual income" means all income from whatever source derived, actually received or anticipated.

"Applicant" means an individual who applies for PAAD, either personally or through an authorized agent.

"Beneficiary" means an individual who has been found eligible for PAAD benefits.

"Calendar year" means a year beginning January 1 and ending on December 31. It is the base period utilized to determine annual income and PAAD eligibility.

"Centers for Medicare and Medicaid Services (CMS)" means the agency of the Federal Department of Health and Human Services which is responsible for the administration of the Medicare program in the United States. CMS was formerly known as the Health Care Financing Administration (HCFA).

"Commissioner" means the Commissioner of the Department of Health and Senior Services.

"Current year" means the calendar year in which a person applies or reapplies for PAAD.

"Department" means the Department of Health and Senior Services.

"Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)" means a type of Medicare Part B coverage that applies to certain types of medical equipment and supplies. Pharmacies enrolling as Medicare Part B suppliers for the purpose of PAAD's Medicare Recovery initiative must enroll under DMEPOS.

"Electronic Data Interchange (EDI) Enrollment Form" means an agreement signed by a Medicare Part B Supplier authorizing PAAD to bill Medicare electronically on its behalf for claims that are eligible under both PAAD and Medicare.

"Expiration date" means the date when a beneficiary's PAAD eligibility ends.

"Initial Prescription Claim" means a PAAD claim for a drug not previously paid by the State during the 200-day calendar period immediately preceding the service date of a claim being considered for payment; or a PAAD claim that exceeds a time period based on the service date of the previously paid PAAD claim.

"Legend drug" means any approved drug product which by Federal law cannot be dispensed without a prescription and bears the statement on the label: "Caution: Federal law prohibits dispensing without a prescription."

"Medicare" means medical assistance provided to certain aged and disabled persons as authorized under Title XVIII (Medicare) of the Social Security Act.

"Medicare Part B Supplier" means a supplier of Medicare Part B (Medical Insurance) services to Medicare beneficiaries including Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

"National Supplier Clearinghouse (NSC)" means the entity that issues Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) supplier authorization **numbers** nationwide to Medicare Part B Suppliers for the Centers for Medicare and Medicaid Services (CMS). The National Supplier Clearinghouse is located at P.O. Box 100142, Columbia, SC 29202-3142.

"NSC Supplier **Number**" means the authorization **number** issued by the National Supplier Clearinghouse (NSC) to a Medicare Part B Supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for the Centers for Medicare and Medicaid Services (CMS).

"Pharmacy" means any pharmacy located in New Jersey, operating under a valid permit from the Board of Pharmacy of the State of New Jersey, which has filed an application and agreement of participation which has been approved by the New Jersey Medicaid Program.

"Prescription drugs" means all approved legend drugs, including any interchangeable drug products contained in the latest list approved and published by the Drug Utilization Review Council in conformance with the provisions of the "Prescription Drug Price and Quality Stabilization Act," and insulin, insulin syringes, insulin needles and certain diabetic testing materials when prescribed.

1. The term "prescription drugs" includes:

i. Any drug product which by Federal law cannot be dispensed unless ordered by a physician, dentist or podiatrist;

ii. Every product considered to be a legend prescription drug which is required by the Federal Food, Drug and Cosmetic Act to have the following statement on the manufacturer's original packaging label: "Caution: Federal law prohibits dispensing without a prescription";

iii. Insulin, insulin syringes and insulin needles. While not legend drugs, these items are covered by this program when prescribed;

iv. Diabetic testing materials including blood glucose reagent strips which can be visually read, urine monitoring strips, tapes and tablets and bloodletting devices and lancets (electronically monitored devices are not included); and

v. Syringes and needles for injectable medicines for the treatment of multiple sclerosis.

2. The term "prescription drugs" excludes cosmetic drugs as indicated at N.J.A.C. 8:83C-1.15 unless medically necessary.

"Previous year" means the calendar year preceeding the year in which the person is applying or reapplying for PAAD. For example, 1995 is the "previous year" when referring to an application which is dated between January 1, 1996 through December 31, 1996, inclusive.

1. If a person, who is required to submit a Federal, State and/or City Income Tax return, applies for PAAD at the beginning of a calendar year but has not yet filed an income tax return for the previous year, the last year for which the person filed a tax return is considered to be the "previous year" when completing the PAAD application.

"Provider" means any individual, partnership, association, corporation, institution, or any other public or private entity, agency, or business concern, meeting applicable requirements and standards for participation in the New Jersey Medicaid Program, and the Pharmaceutical Assistance to the Aged and Disabled Program, and where applicable, holding a current valid license, and lawfully providing medical care, services, goods and supplies authorized under N.J.SA. 30:4D-1 et seq. and amendments thereto.

"Refill Prescription Claim" means a PAAD claim for a previously paid prescription in which the time period between claims is less than or equal to two times the days supply reported by the previously paid PAAD claim for the same prescription. A refill prescription claim may have the same or different prescription **number**.

"Resident" means "one legally domiciled within the State (of NJ) for a period of 30 days immediately preceding the date of application for inclusion in the PAAD Program. Mere seasonal or temporary residence within the State, of whatever duration, does not constitute domicile." (See N.J.A.C. 8:83-6.4 for residence requirements.)

<< NJ ADC 8:83C-1.2 >>

<< NJ ADC 8:83C-1.3 >>

8:83C-1.2-1.3 Participation of eligible providers

(a) (No change.)

(b) To be approved as a provider of pharmaceutical services, the pharmacy shall:

1. (No change.)

2. File an application and sign an agreement with the Department of Human Services (DHS), Division of Medical Assistance and Health Services (DMAHS).

i. All new PAAD/Medicaid provider applications from a prospective PAAD pharmacy provider (Form FD-29) shall list the pharmacy's NSC Supplier **Number** or include a statement that the pharmacy has applied for a NSC Supplier **Number**. Proof of the assigned NSC Supplier **Number** or of application for a NSC Supplier **Number** as listed in (c) below shall be provided with the application.

i.-ii. (No change in text.)

3. (No change.)

4. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier, provide proof of such enrollment to PAAD, an authorized PAAD to bill eligible claims

electronically on the pharmacy's behalf as a billing agent for those claims that are dually eligible for both PAAD and Medicare (see N.J.A.C. 8:83C-1.4, Medicare recovery initiative).

(c) To ensure continued enrollment as a PAAD-participating pharmacy, a pharmacy shall:

1. Establish and maintain active enrollment as a Medicare Part B DMEPOS Supplier by obtaining a NSC Supplier **Number** from the National Supplier Clearinghouse (NSC) or other appropriate agent of the Centers for Medicare and Medicaid Services (CMS);

2. Provide proof of such enrollment to PAAD in the form of either:

i. A copy of a recent Medicare Part B remittance letter, with the NSC Supplier **Number** clearly indicated;

ii. A copy of a recently submitted original CMS 1500 claim form, with the NSC Supplier **Number** clearly indicated;

iii. A copy of the approval letter from NSC containing the assigned NSC Supplier **Number**;

iv. If an approval letter has not yet been received from NSC, a copy of the completed application form CMS 855s can be submitted to show that a good faith effort is being made to obtain a NSC Supplier **Number**;

3. Complete and return an EDI Enrollment Form, included with the provider enrollment packet, authorizing PAAD to bill Medicare electronically for eligible claims; and

4. Comply with Medicare dispensing and documentation requirements as described in Medicare's Supplier Manual.

<< NJ ADC 8.83C-1.4 >>

8.83C-1.4 Medicare recovery initiative

(a) PAAD beneficiaries are required to authorize assignment of benefits to the State of New Jersey for any plan of assistance or insurance that covers the cost of prescription drugs at least in part. (See N.J.A.C. 8:83-6.9, Authorization.) The Medicare Recovery initiative was established to allow PAAD to recoup the cost of prescription drug benefits payable under Medicare Part B.

(b) All New Jersey pharmacies that participate in the PAAD program are mandated to comply with the requirements of the Medicare recovery initiative as a condition of continued participation.

1. Pharmacies shall enroll as Medicare Part B DMEPOS suppliers and maintain active status. Proof of Medicare enrollment shall be supplied to PAAD as described in N.J.A.C. 8:83C-1.3(c)2.

2. Pharmacies shall comply with all Medicare documentation requirements as described in the Medicare Supplier Manual, including ensuring that the patient's diagnosis code is recorded by the doctor on every Medicare-eligible written order, and retaining records for the specified period of time.

(c) Recoupment of PAAD's expenditures for Medicare-eligible drugs and supplies is made using the following procedures:

1. When pharmacies submit claims to PAAD, the point-of-sale system identifies those claims that are potentially eligible for reimbursement by Medicare. The pharmacy is notified to maintain Medicare documentation requirements for these claims via an edit code returned by the system.

2. PAAD, acting as a billing agent for the pharmacies under 42 C.F.R. § 424.73, submits eligible claims to Medicare.

3. Medicare pays its allowable amount for eligible claims directly to the pharmacies.

4. PAAD collects the reimbursement by withholding the amount of the Medicare payments from future PAAD remittances.

<< NJ ADC 8:83C-1.3 >>

<< NJ ADC 8:83C-1.5 >>

8:83C-1.3-1.5 Conditions for participation as a provider of pharmaceutical service

(a) (No change.)

(b) All drugs must be prescribed.

1. "Prescribed drugs" means simple or compounded substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are:

i. (No change.)

ii. Dispensed by licensed pharmacists in accordance with regulations promulgated by the New Jersey State Board of Pharmacy, N.J.A.C. 13:39; and additional prescription pricing in accordance with P.L. 1994, c.67, as revised by P.L. 1995, c.5 (see N.J.A.C. 8:83C-1.13(b)-1.15(b)+>>); and

iii. (No change.)

(c) (No change.)

<< NJ ADC 8:83C-1.4 >>

<< NJ ADC 8:83C-1.6 >>

8:83C-1.4-1.6 Program restrictions affecting payment for prescribed drugs

(a) The choice of prescribed drugs shall be at the discretion of the prescribed within the limits of applicable laws. However, the prescriber's discretion is limited for certain drugs. Reimbursement may be denied if the requirements of the following rules are not met:

1. Covered and non-covered pharmaceutical services as listed in N.J.A.C. 8:83C-1.12-1.14 and 1.13-1.15, respectively;

2. Quantity of medication (see N.J.A.C. 8:83C-1.14-1.16);

3. Pharmaceutical services requiring pharmacist intervention as part of the PAAD Prospective Drug Utilization Review (PDUR) program (see N.J.A.C. 8:83C-1.26-1.28);

4. Dosage and directions (see N.J.A.C. 8:83C-1.15-1.17);

5. Telephone-rendered original prescriptions (see N.J.A.C. 8:83C-1.16-1.18);

6. Changes or additions to the original prescription (see N.J.A.C. 8:83C-1.17-1.19);

7. Prescription refill (see N.J.A.C. 8:83C-1.18-1.20);

8. Prescription Drug Price and Quality Stabilization Act (N.J.S.A. 24:6E-1 et seq.) (see N.J.A.C. 8:83C-1.19-1.21);

i. (No change.)

ii. Non-Proprietary or generic dispensing (see N.J.A.C. 8:83C-1.10-1.12);

9. Federal regulations (42 C.F.R. 447.301, 331-333) that set the aggregate upper limits on payment for certain multi-source drugs if Federal Financial Participation (FFP) is to be made available. The limit applies to all "maximum allowable cost" drugs (see N.J.A.C. 8:83C-1.5-1.7, Basis of payment); and

10. Drug Efficacy Study Implementation (DESI): "Less than effective drugs" subject to a Notice of Opportunity for Hearing (NOOH) by the Federal Food and Drug Administration (see N.J.A.C. 8:83C-1.20-1.22) and listing of DESI drugs in (N.J.A.C. 10:51, Appendix A).

<< NJ ADC 8:83C-1.5 >>

<< NJ ADC 8:83C-1.7 >>

8:83C-1.5-1.7 Basis of payment

(a) This section provides a summary of the elements involved in the calculations of the payment of legend or certain non-legend drugs. The elements include the following:

1. Program restrictions affecting reimbursement for the dispensing of drugs as listed in N.J.A.C. 8:83C-1.4-1.6;

2. Price information as supplied from a reference drug file subcontracted for this purpose by the fiscal agent and accepted by the Division of Medical Assistance (Medicaid) as the primary source of pricing information for the New Jersey Medicaid Management Information System (NJMMIS). The drug price shall not exceed the lower of the average wholesale price minus 10 percent as supplied by the reference drug file contractors; the provider's usual and customary charge; or the drug's maximum allowable cost, if applicable (see (b) below);

i. The NJMMIS reference drug file is updated periodically by the fiscal agent based upon data supplied by First Data Bank (FDB). The update process provides the fiscal agent with current data to include changes in product description. Providers are made aware of therapeutic indications for various classes of drugs by product literature distributed by drug manufacturers and by various trade publications. Based on market information, providers can determine whether a product's therapeutic classification meet the criteria specified in N.J.A.C. 8:83C-1.12-1.14, (Covered pharmaceutical services).

3.-4. (No change.)

(b) Payment for legend drugs is based upon the maximum allowable cost. This means the lower of the upper payment limit price list (MAC price) as published by the Federal government or the average wholesale price (AWP). See N.J.A.C. 10:51, Appendix B, for the listing of MAC drugs.

1. (No change.)

2. For information about the "regression categories and discounts," see N.J.A.C. 8:83C-1.6-1.8 and for usual and customary charge, see N.J.A.C. 8:83C-1.11-1.13.

3. (No change.)

(c)-(f) (No change.)

<< NJ ADC 8:83C-1.6 >>

<< NJ ADC 8:83C-1.8 >>

8:83C-1.6-1.8 Regression categories and discounts

(a) For pharmaceutical services provided prior to July 15, 1996, the maximum cost for each eligible prescription claim not covered by the maximum allowable cost price (see N.J.A.C. 8:83C-1.5-1.7, Basis of payment) shall be subject to the following fiscal conditions based upon six categories. The category, as determined by the New Jersey Medicaid program, is based on the previous year's total prescription **volume** for each participating pharmacy. The categories shall be reviewed annually and adjusted as appropriate.

1. (No change.)

(b) For pharmaceutical services provided prior to July 15, 1996, the pharmacy provider shall submit, in writing, an annual report on form FD-70 (See N.J.S.A. 10:51, Appendix C, Pharmacy Provider Certification Statement) certifying its prescription **volume**. The Division of Medical Assistance (Medicaid) shall determine a provider's total prescription **volume**, which includes all prescriptions filled (both new and refills), including nursing facility prescriptions, for private patients, Medicaid, PAAD, and other third party recipients for the previous calendar year. Failure to submit this report annually shall result in the provider being placed in the maximum discount category (category VI) for the year of non-compliance, or until the required report is received.

1. Category I: Pharmacies whose total prescription **volume** in the preceding calendar year was not more than 14,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-basis-1.7, Basis of payment, as the maximum.

2. Category II: Pharmacies whose total prescription **volume** in the preceding calendar year was at least 15,000 but not more than 19,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-1.7, less three percent, as the maximum.

3. Category III: Pharmacies whose total prescription **volume** in the preceding calendar year was at least 20,000 but not greater than 29,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-1.7, less three percent, as the maximum.

4. Category IV: Pharmacies whose total prescription **volume** in the preceding calendar year was at least 30,000 but not greater than 39,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-1.7, less four percent, as the maximum.

5. Category V: Pharmacies whose total prescription **volume** in the preceding calendar year was at least 40,000 but not greater than 49,999 prescriptions.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-1.7, less five percent, as the maximum.

6. Category VI: Pharmacies whose total prescription **volume** in the preceding calendar year was at least 50,000 prescriptions or more.

i. Pharmacy providers in this category shall receive reimbursement for PAAD prescription claims for legend drugs, at average wholesale price (AWP), as defined in N.J.A.C. 8:83C-1.5-1.7, less six percent, as the maximum.

ii. (No change.)

7. (No change.)

(c) (No change.)

<< NJ ADC 8:83C-1.7 >>

<< NJ ADC 8:83C-1.9 >>

8:83C-1.7-1.9 (No change in text.)

<< NJ ADC 8:83C-1.8 >>

<< NJ ADC 8:83C-1.10 >>

8:83C-1.8-1.10 PAAD program copayment

(a) Beneficiaries in the PAAD program are responsible for a part of the cost of drugs and devices covered by the PAAD program. At the point of sale, a PAAD beneficiary shall render to a pharmacy provider a fixed or adjustable copayment of an amount determined appropriate by the Legislature (see N.J.A.C. 8:83C-1.19(a)4-1.21(a)4).

(b) (No change.)

(c) The beneficiary co-payment amount shall not be affected by a claim's eligibility for submission to Medicare for reimbursement (see N.J.A.C. 8:83-1.4, Medicare recovery initiative).

<< NJ ADC 8:83C-1.9 >>

<< NJ ADC 8:83C-1.11 >>

8:83C-1.9-1.11 Compounded prescriptions

(a) (No change.)

(b) Claims for compounded prescriptions may be manually or electronically submitted to the fiscal agent through a point-of-sale (POS) claim adjudication system approved by the PAAD program. (See N.J.A.C. 8:83C-1.25-1.27).

1. (No change.)

(c) Reimbursement for compound prescriptions shall not exceed the lower of:

1. The cumulative cost of the active ingredient(s), as described in N.J.A.C. 8.83C-1.5-1.7, and/or pharmaceutical excipient(s), plus a dispensing fee, as described in N.J.A.C. 8:83C-1.7-1.9; or

2. (No change.)

(d) (No change.)

(e) Reimbursement for compounded prescriptions submitted manually or as an EMC claim is calculated based on the ingredient cost, as described in N.J.A.C. 8:83C-1.5-1.7, of the most costly active ingredient, plus a dispensing fee, as described in N.J.A.C. 8:83C-1.7-1.9.

1. For compounded prescriptions without an active ingredient(s), reimbursement is based on (d) above, plus a dispensing fee, as described in N.J.A.C. 8:83C-1.7-1.9.

(f) The maximum charge for a compounded prescription must not exceed the limits set forth in N.J.A.C. 8:83C-1.14-1.16.

(g) Restrictions on payments for compounded prescriptions are as follows:

1. All legend ingredients which are contained in compounded prescriptions must be covered by the PAAD program. If a legend drug is a DESI (Drug Efficacy Study Implementation, see N.J.A.C. 8:83C-1.20-1.22) drug, the compounded prescriptions are not covered.

2. Compounded prescriptions containing drugs not eligible for reimbursement under N.J.A.C. 8:83C-1.13-1.15 are not covered.

<< NJ ADC 8:83C-1.10 >>

<< NJ ADC 8:83C-1.12 >>

8:83C-1.10-1.12 (No change in text.)

<< NJ ADC 8:83C-1.11 >>

<< NJ ADC 8:83C-1.13 >>

8:83C-1.11-1.13 Provider's usual and customary charge or advertised charge

(a) The provider's usual and customary charge or advertised charge is an element considered in the calculation of the basis of payment for legend drugs (see N.J.A.C. 8:83C-1.5-1.7, Basis of payment).

(b) (No change.)

<< NJ ADC 8:83C-1.12 >>

<< NJ ADC 8:83C-1.14 >>

8:83C-1.12-1.14 (No change in text.)

<< NJ ADC 8:83C-1.13 >>

<< NJ ADC 8:83C-1.15 >>

8:83C-1.13-1.15 Non-covered pharmaceutical services

(a) The following classes of prescription drugs or conditions are not covered under the PAAD program:

1.-11. (No change.)

12. Drugs for which Federal Financial Participation (FFP) is not available, including:

i. Drug Efficacy Study Implementation (DESI) drugs and identical, similar and related drugs (see N.J.A.C. 8:83C-1.20-1.22);

13. Any bundled drug service, except drug product cost which is a component of a bundled drug service (see N.J.A.C. 8:83C-1.21-1.23);

14.-15. (No change.)

(b) Otherwise reimbursable products shall be excluded from payment, under the following condition(s):

1. Products whose costs are found to be in excess of defined costs outlined in N.J.A.C. 8:83C-1.5-1.7, Basis of payment;

2.-4. (No change.)

5. A prescription refilled too soon as described in N.J.A.C. 8:83C-1.18(a)5-1.20(a)5;

6. Drug products denied payment based on point-of-sale (POS) and prospective drug utilization review (PDUR) standards adopted by the PAAD program. (See N.J.A.C. 8:83C-1.26-1.28);

7. (No change.)

8. Cosmetic drugs including drugs used in the treatment of baldness, age spots and weight loss unless medically necessary. The MEP specified at N.J.A.C. 8:83C-1.27-1.29 shall be followed to confirm medical necessity.

<< NJ ADC 8:83C-1.14 >>

<< NJ ADC 8:83C-1.16 >>

8:83C-1.14-1.16

(a) (Reserved) - Public Law 1998, c.124 establishes different days supply requirements for pharmacy claims based on the drug use history of a PAAD beneficiary. Days supply limitations for an Initial Prescription Claim for PAAD beneficiaries shall be different from days supply limitations for a Refill Prescription Claim.

1. The following days supply limitations shall apply to PAAD claims:

i. The days supply limitation for an Initial Prescription Claim shall be limited to a **34**-day supply; and

ii. The days supply limitation for a Refill Prescription Claim shall be limited to a **34**-day supply or 100 dosage units, whichever is greater.

(b)-(c) (No change.)

(d) Prescriptions shall not be split or reduced in quantity, unless the quantity prescribed exceeds Program limits, in which case the quantity shall be reduced to Program limits described in (a) above.

1. (No change.)

2. When the item prescribed is packaged from the manufacturer in quantities higher than PAAD limits, PAAD will waive the **34**-day requirement limit for the reimbursement and allow the prepackaged quantity.

(e) The quantity of medication dispensed shall not be affected by a claim's eligibility for submission to Medicare for reimbursement, except where Medicare dispensing guidelines allow a greater than **34**-day supply for an initial prescription and the item being dispensed is packaged from the manufacturer in quantities consistent with Medicare dispensing guidelines. In such cases, PAAD will waive the **34**-day limit and follow Medicare dispensing guidelines (see N.J.A.C. 8:83C-1.4, Medicare recovery initiative).

<< NJ ADC 8:83C-1.15 >>

<< NJ ADC 8:83C-1.16 >>

<< NJ ADC 8:83C-1.17 >>

<< NJ ADC 8:83C-1.18 >>

<< NJ ADC 8:83C-1.19 >>

<< NJ ADC 8:83C-1.20 >>

Recodify existing N.J.A.C. 8:83C-1.15 through 1.18 as 1.17 through 1.20 (No change in text.)

<< NJ ADC 8:83C-1.19 >>

<< NJ ADC 8:83C-1.21 >>

8:83C-1.19-1.21 Prescription Drug Price and Quality Stabilization Act

(a) The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., shall apply to the PAAD program. This law requires that every prescription blank contain the statements "Substitution Permissible" and "Do Not Substitute." The prescriber shall initial one of the statements in addition to signing the prescription blank.

1.-4. (No change.)

5. For non-MAC drugs (see N.J.A.C. 8:83C-1.5-1.7), when the prescriber initials "Do Not Substitute," the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form or the similar field in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC), as defined in N.J.A.C. 8:83C-1.5-1.7 (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).

6. Claims for MAC drugs with service dates on or after July 15, 1996, and in those situations in which a prescriber authorizes, in accordance with (b) below, the dispensing of a brand drug, the pharmacist shall indicate the prescriber's preference by indicating "Medical Certification" on the claim form, or similar field in the EMC claim format and shall dispense and bill PAAD for the prescribed product. Reimbursement will be the estimated acquisition cost (EAC), (see N.J.A.C. 8:83C-1.5-1.7) plus applicable dispensing fee or the usual and customary charge, whichever is less for the product (see N.J.A.C. 10:51, Appendix D, incorporated herein by reference, Fiscal Agent Billing Supplement for instructions about the claim form or N.J.A.C. 10:51, Appendix E, incorporated herein by reference, regarding the proper EMC claim format).

(b) Federal regulations at 42 C.F.R. 447.331 prescribe the aggregate upper limit, or Maximum Allowable Cost (MAC) for certain legend drugs which are applied to Medicaid-covered pharmacy services (see (d) below). For claims with service dates on or after July 15, 1996, these limits shall apply to all MAC drugs (see N.J.A.C. 10:51, Appendix B, incorporated herein by reference) covered by PAAD unless the prescriber indicates in his or her own handwriting on each written prescription or follow-up written prescription to a telephone-rendered prescription (see N.J.A.C. 8:83C-1.5-1.7) the phrase "Brand Medically Necessary." The Federal regulation at 42 C.F.R. 447.331 requires a written statement and does not permit the use of alternatives such as a check-off box initials or prescriber's signature, next to a preprinted statement "Do Not Substitute," nor does it allow a handwritten statement "Do Not Substitute." For purposes of reimbursement, the physician's override capability under N.J.S.A. 24:6E-1 does not apply to drugs which have a Federal MAC limit.

(c)-(d) (No change.)

<< NJ ADC 8:83C-1.20 >>

<< NJ ADC 8:83C-1.22 >>

8:83C-1.20-1.22 (No change in text.)

<< NJ ADC 8:83C-1.21 >>

<< NJ ADC 8:83C-1.23 >>

8:83C-1.21-1.23 Bundled drug service

(a) (No change.)

(b) Bundled drug service shall not be eligible for reimbursement by the PAAD program. The cost of the drug product which is a component of a bundled drug service (see N.J.A.C. 8:83C-1.12-1.14, Covered Pharmaceutical Services) shall be covered by the PAAD program.

1. (No change.)

<< NJ ADC 8:83C-1.22 >>

<< NJ ADC 8:83C-1.23 >>

<< NJ ADC 8:83C-1.24 >>

<< NJ ADC 8:83C-1.25 >>

<< NJ ADC 8:83C-1.26 >>

Recodify existing N.J.A.C. 8:83C-1.22 through 1.24 as 1.24 through 1.26 (No change in text.)

<< NJ ADC 8:83C-1.25 >>

<< NJ ADC 8:83C-1.27 >>

8:83C-1.25-1.27 Point-of-sale (POS) claims adjudication system

(a) (No change.)

(b) In order for a PAAD approved pharmacy provider, in accordance with N.J.A.C. 8:33C-1.3-1.5, to submit pharmacy claims through a POS system, the provider shall enter into an agreement with a POS intermediary or shall directly provide a similar telecommunications network approved by the New Jersey Division of Medical Assistance and Health Services.

1.-3. (No change.)

(c)-(k) (No change.)

<< NJ ADC 8:83C-1.26 >>

<< NJ ADC 8:83C-1.28 >>

8:83C-1.26-1.28 Prospective drug utilization review (PDUR) program

(a) (No change.)

(b) POS participating pharmacy providers shall be required to meet the conditions described in N.J.A.C. 8:83C-1.25-1.27.

(c)-(f) (No change.)

<< NJ ADC 8:83C-1.27 >>

<< NJ ADC 8:83C-1.28 >>

<< NJ ADC 8:83C-1.29 >>

<< NJ ADC 8:83C-1.30 >>

Recodify existing N.J.A.C. 8:83C-1.27 and 1.28 as 1.29 and 1.30 (No change in text.)